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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,853	08/13/2003	Randall V. Sparer	P-10998.00	9178

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/640,853	SPARER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-75 and 78-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-75 and 78-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/20/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/20/2008 has been entered.

Applicants amendments to the claims filed 06/20/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1).

Sirhan teaches a luminal prosthesis that can be in the form of a stent, the stent can further contain a rate-controlling element formed from polymers including cellulose acetate butyrate (CAB), polyethylene vinyl acetate (PEVA), polyurethane, polycarbonates, polymethylmethacrylate and the like and mixtures and combinations

thereof, the rate controlling element provides for a controlled release of at least one active ingredient that can be contained within the element. See abstract, [0046]-[0050],[0053] and claims 1,18,74-76,80-82,112-118 and 126. The active ingredient included numerous therapeutics including dexamethasone, azatioprine and prednisone, all of the above active ingredients are also disclosed as active ingredients within applicants own specification. See claim 18 and [0030]. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Sirhan teaches the use of the same polymers in a mixture with the active agent contained within that the polymer it will provide the same barrier to permeation since the polymers are the same then their release properties will inherently be the same. Regarding the limitations that at least one polymer has a higher diffusivity and one lower then the target diffusivity, this

limitation is met since it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is met, because Sirhan teaches the use of polymeric films within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75 and 78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Sirhan who teaches a method to make the same polymer blend as claimed by applicant, the blend incorporated a bioactive agent, therefore the polymer blend would control the delivery of the bioactive agent in the same way as applicants claims since the same composition will inherently have the same properties. Furthermore regarding new claims 79-88, these method claims are essentially the same as previous independent claims in combination with some of the limitations within the dependent claims, therefore since the examiner has already detailed how the Sirhan reference teaches applicants claimed method of forming a miscible polymer blend for the controlled release of an active ingredient the claims are met as detailed in previous office actions and above.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252).

Hossainy teaches a coating for stents and a method for forming the coated stent having a film forming biocompatible polymer coating in which different polymers may be used for different layers (polyurethanes, polyamides, polyesters, polymethacrylates polyolefins, ethylene methyl methacrylate copolymers various hydrophilic celluloses and many other hydrophobic and hydrophilic polymers were specifically listed) in which the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents (including fluorouracil which is disclosed as an active ingredient within applicants own specification). See col 1 lin 6-9, col 2 lin 9-19, col 4 lin 15-col 5 lin 38, col 7 lin 5-11, lin 56-col 8 lin 35, col 9 lin 20-25, fig. 6 and 7. See col 7 lin 18-55. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Hossainy teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new

function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Hossainy detailed the use of a top coating to delay release of the pharmaceutical agent. Regarding the limitations that at least one polymer has a higher diffusivity and one lower then the target diffusivity is met since the target diffusivity is determined by the preselected time for delivery and the preselected critical dimension of the polymer which is taught by Hossainy; it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. See col 7 lin 18-55, fig. 6 and 7. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is met, because Hossainy teaches the use of polymeric films within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations within claims 75 and 78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active

Furthermore regarding new claims 79-88, these method claims are essentially the same as previous independent claims in combination with some of the limitations within the dependent claims, therefore since the examiner has already detailed how the Hossainey reference teaches applicants claimed method of forming a miscible polymer blend for the controlled release of an active ingredient the claims are met as detailed in previous office actions and above.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483).

Whitbourne teaches a coating for biomedical devices (including stents) and the method to make the coatings in which the coating is a blend of a stabilizing polymer and an active agent comprised of a hydrophilic polymer (the blends can include the following: polyurethanes, acrylic polymers, methacrylic polymers, vinyl acetal polymers, polyethers, PVP, epoxy polymers, several hydrophilic celluloses and numerous other stabilizing and hydrophilic polymers/copolymers) the coating also comprises a bio-active agent contained within (including thymol which is disclosed as an active ingredient within applicants own specification). See col 1 lin 5-12, lin 65-col 2 lin 24, lin 31-38, lin 43-47, col 3 lin 21-59, col 4 lin 13-36, col 5 lin 28, lin 41-46, col 7 lin 15-17, lin 55-56, col 9 lin 29-32, 50-54 and claim 17. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or 3 $J^{1/2}cm^{3/2}$, Whitbourne teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It

appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that "the miscible polymer blend initially provides a barrier to permeation" this limitation is met, since Whitbourne discuses a time-release effect of the active ingredient attributable to the interaction of the bioactive agents with the stabilizing polymer. See col 3 lin 56-59. Regarding the limitation that the swellability for the polymer blend is no more than 10% by volume, this limitation is met, because Whitbourne discusses the swellability of the hydrophilic polymer in the composition, while the patent discussed the swellability in terms of weight not volume it is inherent that by blending with a non-swelling polymer the blend could have swelling of no greater than 10% of its own volume, also since the polymers are the same so will be their physical properties such as swelling. See col 5 lin 1-12. Regarding the limitation that at least one polymer has a higher diffusivity and one lower then the target diffusivity, this is considered inherent by the examiner (see above). Regarding claims 71-74 it is inherent that a stent being an implantable device would deliver any active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations within claims 75 and 78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two

miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Whitbourne who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims. Furthermore regarding new claims 79-88, these method claims are essentially the same as previous independent claims in combination with some of the limitations within the dependent claims, therefore since the examiner has already detailed how the Whitbourne reference teaches applicants claimed method of forming a miscible polymer blend for the controlled release of an active ingredient the claims are met as detailed in previous office actions and above.

Response to Arguments

Applicant's arguments filed 06/18/2008 have been fully considered but they are not persuasive. Applicant's assert that the references above fail to specifically point out and distinctly set forth each and ever feature recited within the claims. Specifically applicants assert that Hossainey teaches over 30 classes of polymers and Whitbourne and Sirhan teaches more than a dozen classes of polymers, thus applicants surmise that each reference specifies a vast number of individual polymer species. Applicants further contend that there is no guidance within either reference to select the same polymer blend claimed by applicants, and they provide no more guidance as to what polymer to select then a mere entry of different polymers in a stockroom. Applicants contend that randomly taking

polymers from a subgenera listed in the claims of the references above will not necessarily result in a combination of polymers that are miscible with each other or have the claimed difference in solubility. Applicants further argue that there is no 35 U.S.C. § 112 1st paragraph support within either reference for applicants claimed invention.

The examiner respectfully disagrees. Firstly with respect to Sirhan the polymer blend described is claimed, all US patents are considered valid thus, there is adequate description and 112 1st paragraph support for the claimed polymers. As mentioned numerous times in actions in the past and again herein both the Hossainey and Whitbourne references clearly teach the same first and second polymers claimed by applicants. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting applicants claimed second polymer and also claims an active agent that included several cellulose derivatives and polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the claims and the description of the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainy appellants claimed drug delivering polymer blend and the method to produce it. Also in regards to Whitbourne and Hossainy, the prior art's mere disclosure of more than one alternative does not constitute a teaching

away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. Furthermore while both the references above teach and claim numerous polymer blends, this only supports the fact that polymer blends are a well known and very mature field. One of ordinary skill in the art would know from the teachings of the references and what is generally well known and established in the art that numerous polymers can be blended or mixed together to form coatings for medical devices. In the same regard applicants specification and claims are also broad in the number of types of polymers that can be blended, but the examiner has concluded that applicants have provided enough written description and showed enablement since the field of polymer blends is well known and very mature field, thus there are currently no 112 1st paragraph rejections over the breadth of the claims. However applicants argue that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible. A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As detailed above the examiner concluded from the prior art that polymer blends used as coatings for medical articles is a very mature field, thus the breadth of the number of possible combinations would not preclude one of ordinary skill in the art from envisioning nearly any combination of polymers that are described as being capable of being blended. Thus the examiner believes there is adequate support and guidance within each reference so that one of ordinary skill in the art would have

readily envisaged applicants claimed invention from the teachings of Hossainey and Whitbourne.

Applicant's assert that the examiner has given no support for his assumption that the polymers described in each reference will have the same solubility parameters especially in view of all the different types of polymers contained within one class of polymers, e.g. MW, degree of crosslinking, glass transition temperature etc.

The examiner respectfully disagrees with applicant's argument above. Applicant's claims as currently amended require a first polymer and a second polymer that is miscible with it, the types of first and second polymers are described throughout the claims and specification. In order to conduct his search the examiner searched for the same polymers that would meet the claimed blend. The examiner did not consider the MW, crosslinking degree, glass transition temperature (although glass transition temperature is well known to be correlated to MW for a given polymer species), since these parameters are not within the claims. The examiner can only search for the claimed subject matter. For examination purposes the examiner concluded that the same polymer will inherently have the same properties. Since the polymers within the references are the same in scope as applicants claimed polymers it is assumed that the properties of the polymers are the same since applicants have not amended their claims in such a way to distinguish the polymers by MW, crosslinking degree ect, that would preclude the prior art references.

Applicants further assert that none of the references above expressly or inherently teach a method that includes forming a miscible polymer blend by the conscious, deliberate and discretionary step of selecting a second polymer based on its miscibility with a poly(ethylene-co-(meth)acrylate) and having the specified difference in solubility parameter compared to poly(ethylene-co-(meth)acrylate). Applicants further argue that they are allowed to have a mental process or abstract idea within their claims since their invention provides a material transformation and produces a useful concrete and tangible result. Thus applicants surmise that for at least this reason selecting the second polymer as recited within applicant's claims must be considered.

The examiner disagrees with applicant's remarks above. Firstly applicants attempt of limiting the independent claims so the second polymer is **selected** to be miscible with the first polymer is a **mental process or abstract idea** and is not a patentable difference in view of the prior art. The reasons to select the polymer blend in the reference above may indeed be different then choosing them based on their miscibility properties, however a **mental process** of **selecting** polymers is not a **patentable distinction** that can preclude applicant's claimed invention from the prior art.

Furthermore it is noted by the examiner that **applicants selection step actually relies on a mathematical formula** in which one of ordinary skill in the art must first find the solubility parameter (δ_d) of a first polymer and then find the solubility parameter of a second polymer, in which the difference of the polymers is no greater than 3 $J^{½}cm^{3/2}$.

Essentially applicants are requiring the selecting step to use a mathematical formula to select appropriate second polymers that are soluble with the first polymer. If the solubility parameter of the first polymer is defined as δ_{d1} and the second polymer as δ_{d2}, since δ_{d1} can be readily found in a table of solubility parameters one would have to find what second polymers could be used to fulfill the limitation that the difference in solubility parameters is no more than 3 $J^{½}cm^{3/2}$ by applying a mathematical formula. For instance the mathematical formula could be construed as:

$\delta_{d1} - \delta_{d2} \leq 3\ J^{½}cm^{3/2}$ or $\delta_{d2} - \delta_{d1} \leq 3\ J^{½}cm^{3/2}$

Since δ_{d1} is known (can be found in solubility parameter table) the formula can be rewritten to solve for the value of δ_{d2} as follows:

$\delta_{d2} \geq -(3\ J^{½}cm^{3/2} - \delta_{d1})$ or $\delta_{d2} \leq 3\ J^{½}cm^{3/2} + \delta_{d1}$

Thus as shown above applicants are essentially claiming a method of selecting a second polymer with a solubility parameter (δ_{d2}) that is miscible with a first polymer based on the solubility parameters of each (δ_{d1} and δ_{d2}) being no more than 3 $J^{½}cm^{3/2}$, however such a step of selecting requires the use of a mathematical formula, which is not statutory subject matter under 35 U.S.C. 101, thus the examiner cannot consider it as a patentable distinction.

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. 101 (i.e., process, machine, manufacture, or composition of matter) does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. Diehr, 450 U.S. at

185, 209 USPQ at 7;accord, e.g., Chakrabarty, 447 U.S. at 309, 206 USPQ at 197; Parker v. Flook, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); Benson, 409 U.S. at 67-68 , 175 USPQ at 675; Funk, 333 U.S. at 130, 76 USPQ at 281. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." Le Roy, 55 U.S. (14 How.) at 175. Instead, such "manifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." Funk, 333 U.S. at 130, 76 USPQ at 281. "Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." Ibid. Nor can one patent "a novel and useful mathematical formula," Flook, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam power, O 'Reilly v. Morse, 56 U.S. (15 How.) 62, 113-114(1853); or "[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals," Funk, 333 U.S. at 130, 76 USPQ at 281; see Le Roy, 55 U.S. (14 How.) at 175.

Since mental processes or abstract ideas of selecting a polymer and mathematical formulas are not patentable material and cannot be considered as limitations, the examiner conducted his search of the prior art on a method of making a device containing a blend of two polymers and an active agent that are within the scope of applicant's claims. The examiner concluded that a method of forming an active agent delivery system comprising a polymer blend does have utility, thus the examiner has never rejected applicant's claims under 35 U.S.C. §101, however the examiner cannot consider limitations that do not lead to a patentable distinction, **a mathematical**

formula, an abstract idea or mental process limitation within a claim set is not a patentable distinction that the examiner can consider when applying prior art. Thus since as previously stated all of the above references teach a process to make the same polymer blend containing the same active ingredients as applicant's claims the limitations are met. The subject matter courts have found to be outside of or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See MPEP § 2106.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1).

Sirhan is disclosed above. The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Sirhan encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1,

submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081] within Perez. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252).

Hossainy is disclosed above. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Hossainy encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in

the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483).

Whitbourne is disclosed above. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Whitbourne encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030]

and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Response to Arguments

Applicant's arguments filed 06/18/2008 have been fully considered but they are not persuasive.

Applicant's assert that the references above fail to teach or suggest all of the recited features within the claims, specifically as in the arguments summarized above applicant's assert that none of the references teach or suggest selecting polymers based upon their miscibility or difference in solubility parameters.

For the same reasons as outlined above the examiner disagrees, the remarks by the examiner above for the process of selecting a polymer based upon its miscibility is incorporated herein. Essentially the abstract ides or mental process of selecting a

polymer based upon its miscibility and mathematical formula are not a limitation that the examiner considered when applying the prior art.

Applicants assert as above that the references do not provide a teaching or suggestion that would lead one skilled in the art to select applicants claimed subset of polymer combinations from among the innumerable generic polymer combinations.

The examiner for the reasons detailed above disagrees. As above within the Sirhan reference the polymer mixture is claimed and all US Patents are considered valid. As detailed above both the Hossainey and Whitbourne references disclose the same polymer combination claimed by applicants. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"... *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Also as noted above since the field of polymer blends useful as coatings for medical articles is a well known and mature field one of ordinary skill in the art would have a reasonable expectation of success in successfully blending any two polymers from a Markush type group that were disclosed as being capable of blending (mixing) together as described by Hossainey and Whitbourne.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618